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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/948,149	10/09/1997	BRIAN M. FENDLY	P1053R2	6683

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[REDACTED] EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
1645	36

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	08/948,149	FENDLY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18November2002.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 28-40 and 42-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 28-40,42-62 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)                  4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                  5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 33.                  6) Other: \_\_\_\_\_

Art Unit: 1645

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 18November2002, paper#32, is acknowledged.
2. Applicants' Supplemental Response, received 18December2002, paper#35, is acknowledged.
3. Currently, claims 28-40 and 42-62 are pending and under consideration.

### **Rejections Maintained**

4. The rejection of claims 28-31, 37-38, 40, 56, and 57 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991) is maintained.

Applicants argue that antibodies 7F3 and 7C2 were not publicly available more than one year prior to October 18, 1996 because of the Material Transfer Agreement of Genentech, and therefore the cited reference does not qualify as prior art. A Declaration by Gail D. Phillips, one of the inventors, states that the antibodies were not available.

The examiner has considered the argument concerning a MTA, but does not find it persuasive. First, applicants did not provide a copy of the Genentech MTA for the examiner to assess, but instead provided statements by the inventors interpreting the conditions of the MTA. Second, based upon the inventors' statements, the antibodies were publicly available, albeit with some restrictions for their use. The **statements do not indicate that anyone in the public**

Art Unit: 1645

**could not obtain** the antibodies, just that such acquisition was accompanied with restrictions on their use.

Applicants argue that Shepard et al fails to anticipate the claimed invention and actually teaches away from applicants' surprising discovery. Shepard discusses the claimed antibodies as being less active in "inhibition of proliferation" and does not teach a method for "inducing cell death" as claimed by applicants.

The examiner has considered applicants' argument, but does not find it persuasive. While another antibody, 4D5, may exhibit better activity, Shepard et al does teach that the claimed antibodies also exhibit the required activity. The instant claims are drawn to a method comprising exposing a cell which over expresses ErbB2 to an isolated antibody that binds to an epitope on ErbB2 to which antibody 7C2 or 7F3 bind. Because the antibodies in the instant claims and the antibodies utilized by Shepard et al are one and the same antibodies, i.e., 7C2 and 7F3, the reference does teach identical binding and therefore, identical activity.

5. The rejection of claims 28-31, 37-38 and 40 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) is maintained.

Applicants argue that while Lewis et al discloses antibodies 7C2 and 7F3 in passing, they do not teach or suggest methods of inducing cell death by exposing a cell that over expresses ErbB2 to an antibody that binds to the epitope on ErbB2 to which antibody 7C2 or 7F3 binds.

Art Unit: 1645

Applicants argue that a statement that antibodies that bind to the same epitope inherently have the same properties is insufficient to draw a conclusion that all antibodies that bind to Domain 1 will necessarily have the same characteristics.

The examiner has considered applicants' argument, but does not find it persuasive. Lewis et al utilize not just any antibody which happens to bind to the same epitope, but because: 1) the instant invention and the cited reference list Genentech as the research laboratory, 2) Brian M. Fendly of Genentech is one of the authors of the cited reference and one of the inventors of the instant application, and 3) the antibody designations are identical, it is assumed that Lewis et al **utilize the same antibody as in the instant claims, i.e., 7C2 and 7F3.** Therefore, the antibodies would exhibit the same characteristics because they are the same antibodies.

6. The rejection of claims 32-36, 39, and 58 under 35 U.S.C. 103(a) as being unpatentable Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991), or Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993), in view of Fendly et al (*Cancer Research*, 50:1550-1558, 1990), Deshane et al (*J. Invest. Med.*, 43(Suppl 2):328A, 1995), and further in view of Senter et al (U.S. Pat. No. 4,975,278) is maintained.

Applicants argue that all arguments presented above with regard to Shepard et al and Lewis et al are equally applicable to the rejections of the claims cited in this rejection.

The examiner has considered applicants' argument concerning Shepard et al and Lewis et al, but do not find them persuasive for the reasons put forth above.

Art Unit: 1645

Applicants argue that Fendly et al, Deshane et al, and Senter et al do not make up for deficiencies in Shepard et al and Lewis et al, and therefore the combination of cited references neither teaches nor suggest the present invention.

The examiner has considered applicants' argument, but does not find it persuasive for reasons put forth in the original rejection.

7. The rejection of claims 42-55 and 59-62 under 35 U.S.C. 103(a) as being unpatentable Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991), in view of Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) and Fendly et al (*Cancer Research*, 50:1550-1558, 1990), and further in view of Deshane et al (*J. Invest. Med.*, 43(Suppl 2):328A, 1995) and Senter et al (U.S. Pat. No. 4,975,278) is maintained.

Applicants argue that all arguments presented above with regard to Shepard et al and Lewis et al are equally applicable to the rejections of the claims cited in this rejection.

The examiner has considered applicants' argument concerning Shepard et al and Lewis et al, but do not find them persuasive for the reasons put forth above.

Applicants argue that Fendly et al, Deshane et al, and Senter et al do not make up for deficiencies in Shepard et al and Lewis et al, and therefore the combination of cited references neither teaches nor suggest the present invention.

The examiner has considered applicants' argument, but does not find it persuasive for reasons put forth in the original rejection.

Art Unit: 1645

### **Conclusion**

**8.** No claims are allowed.

**9.** **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**10.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Application/Control Number: 08/948,149

Page 7

Art Unit: 1645

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.



RODNEY P SWARTZ, PH.D

PRIMARY EXAMINER

Art Unit 1645

February 24, 2003